EXHIBIT F

(PART 1)

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ASTRAZENECA PHARMACEUTICALS LP
AND ASTRAZENECA LP

I. PREAMBLE

AstraZeneca Pharmaceuticals LP and AstraZeneca LP hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by their officers, employees, agents and Contractors (as defined herein) (collectively "AstraZeneca"), with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). Contemporaneously with this CIA, AstraZeneca is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Contemporaneously with this CIA, AstraZeneca is also entering or will enter into settlement agreements with various States, and AstraZeneca's agreement to this CIA is a condition precedent to those agreements.

Prior to the effective date of this CIA, AstraZeneca established a voluntary compliance program, which includes a corporate compliance officer and compliance committee, a Code of Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by AstraZeneca, to promote compliance with applicable laws and the promotion of high ethical standards. AstraZeneca agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. AstraZeneca may modify its voluntary compliance measures as appropriate, but, at a minimum, AstraZeneca will ensure that, during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA The period of the compliance obligations assumed by AstraZeneca under this CIA shall be 5 years from the effective date of this CIA (unless otherwise specified). The effective date ("Effective Date") of this CIA shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

Sections VII, VIII, IX, X and XI expire no later than 120 days after the OIG's receipt of: (1) AstraZeneca's final Annual Report; or (2) any additional materials submitted by AstraZeneca pursuant to OIG's request, whichever is later.

The scope of this CIA shall be governed by the following definitions:

1. "Contractor" is any individual who, pursuant to the terms of any contract or written agreement with AstraZeneca for the provision of services (excluding legal services), sells or markets Government Reimbursed Products on behalf of AstraZeneca; calculates or reports prices; and/or negotiates, implements, or reports information related to, government contracts relating to Federal health care programs, including Medicare and the Medicaid Rebate program (codified at 42 U.S.C. § 1396r-8 et seq.), or contracts with the United States Department of Defense.

2. "Covered Products" means the AstraZeneca products listed in Appendix A for which AstraZeneca will report Average Sale Prices in accordance with section III.D below.

3. "Government Reimbursed Products" means AstraZeneca products for which Federal health care programs provide reimbursement.

4. "Covered Persons" includes all Contractors (as defined above) of AstraZeneca located in the United States. "Covered Persons" also includes all officers, employees, and agents of AstraZeneca located in the United States whose job responsibilities relate to: (1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for purposes of Federal health care programs, including, but not limited to, Medicare and the Medicaid Rebate Program; or (3) the

negotiation, implementation, and any reporting of information related to, government contracts.[1]

III. CORPORATE INTEGRITY OBLIGATIONS

AstraZeneca hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* AstraZeneca presently has a Compliance Officer and AstraZeneca shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for overseeing the development of and coordinating the implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer is, and shall continue to be, a member of senior management of AstraZeneca, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the AstraZeneca Leadership Team (AZLT) and shall make at least annual reports regarding compliance matters to the Board of Directors of AstraZeneca PLC.[2] In addition, the Compliance Officer shall provide a copy of the CIA and the Annual Reports relating to the CIA to the Board of Directors and shall annually report to the Board about AstraZeneca's compliance with the terms of this CIA. The Compliance Officer shall be authorized to report on compliance matters to the Board of Directors at any time. The Compliance Officer, with assistance from the Senior Director of Corporate Compliance, shall be responsible for monitoring the day-to-day compliance activities engaged in by AstraZeneca as well as for any reporting obligations created under this CIA.

AstraZeneca shall report to the OIG, in writing, any changes in the identity of, or any material changes in the position description of, the Compliance Officer, or any material actions or changes that would affect the Compliance Officer's ability to perform

1 Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of entities with which AstraZeneca has agreements to co-promote its products. AstraZeneca shall, however, in good faith seek to obtain assurances that such personnel have received appropriate training on proper marketing and sales techniques. The term "Covered Persons" specifically includes all other personnel, apart from those acting under co-promotion agreements, who comprise AstraZeneca's contract sales force, if any.

2 AstraZeneca PLC is a pharmaceutical company headquartered in England, of which AstraZeneca Pharmaceuticals LP and AstraZeneca LP are indirect subsidiaries.

the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Business Compliance Committee.* Prior to the Effective Date, AstraZeneca established a Business Compliance Committee. It shall maintain the Business Compliance Committee during the term of this CIA. The Compliance Committee includes, and shall continue to include (at a minimum), the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments such as Sales and Marketing, Internal Audit, Human Resources). The Compliance Officer shall continue to chair the Business Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of AstraZeneca's risk areas and shall oversee monitoring of internal and external audits and investigations).

AstraZeneca shall report to OIG, in writing, any material changes in the composition of the Business Compliance Committee, or any material actions or changes that would affect the Business Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change. Notwithstanding this notice, AstraZeneca is authorized to modify the structure or function of the Business Compliance Committee consistent with the terms of the CIA.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, AstraZeneca established a written Code of Conduct. Within 120 days after the Effective Date, AstraZeneca shall redistribute its Code of Conduct with an accompanying letter to all Covered Persons and have each Covered Person certify, in writing or electronically, that he or she has received, read, understood and shall abide by the letter and the Code of Conduct. AstraZeneca may distribute the Code of Conduct and the accompanying letter to each individual Covered Person either electronically or in hard-copy form. AstraZeneca shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. AstraZeneca's commitment to full compliance with all Federal health care program requirements, including its commitment to report prices for and market and sell its Government Reimbursed

Products in accordance with Federal health care program requirements;

b. AstraZeneca's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with AstraZeneca's own Policies and Procedures as implemented pursuant to section III.B.2 (including the requirements of this CIA);

c. the requirement that all of AstraZeneca's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individuals designated by AstraZeneca suspected violations of any Federal health care program requirements or of AstraZeneca's own Policies and Procedures;

d. the possible consequences to both AstraZeneca and Covered Persons of failure to comply with all Federal health care program requirements and with AstraZeneca's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in section III.F, and AstraZeneca's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

AstraZeneca shall revise and distribute its Code of Conduct to all Covered Persons at the next scheduled printing of the Code of Conduct or within one year after the Effective Date, whichever is later. The revised code of Conduct shall include, at a minimum, the topics set forth in items (a) through (e) above. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

AstraZeneca shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understood and will

abide by the revised Code of Conduct within 30 days after the distribution of such revisions.

2. *Policies and Procedures*. To the extent not already accomplished, within 120 days after the Effective Date, AstraZeneca shall implement written policies and procedures regarding the operation of its compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1;

b. the calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including the Centers for Medicare & Medicaid Services ("CMS"), the State Medicaid programs, and the drug price reporting services on which government agencies now rely (i.e., First DataBank Inc., the Red Book, etc.) or shall rely in the future;

c. the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, codified at 42 U.S.C. § 1396r-8;

d. the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 353; and

e. measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal anti-kickback statute, codified at 42 U.S.C. §§ 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

Within 120 days after the Effective Date, to the extent not already accomplished, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on AstraZeneca's intranet or other internal web site available to all employees. If AstraZeneca uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), AstraZeneca shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under section III.C of this CIA may be provided by supervisory employees or outside consultant trainers selected by AstraZeneca and/or through electronic or any other effective means. Persons providing the training must be knowledgeable about the subject areas of their training. AstraZeneca may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this section III.C shall mean "normative hours" as that term is used in the computer-based training industry. If AstraZeneca chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training.

AstraZeneca shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, or any other relevant information.

New Covered Persons shall receive the training outlined below in sections III.C.2 and III.C.3 within 60 days after becoming Covered Persons or within 120 days

after the Effective Date, whichever is later. An AstraZeneca employee who has completed the training shall review a new Covered Person's work, to the extent that the work relates to the marketing or sales of Government Reimbursed Products; the calculating or reporting of prices for Government Reimbursed Products; or the fulfillment of any responsibilities relating to the Medicaid Drug Rebate program until such time as the new Covered Person completes the applicable training.

2. *Training Provided to Covered Persons.* Within 120 days after the Effective Date, AstraZeneca shall provide at least four hours of training to each Covered Person. This training, at a minimum, shall explain:

a. AstraZeneca's CIA requirements;

b. AstraZeneca's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues);

c. proper methods of marketing and selling Government Reimbursed Products in accordance with all applicable statutes, regulations and requirements, including, but not limited to, the Federal anti-kickback statute and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples);

d. the personal obligation of each individual involved in marketing and sales of Government Reimbursed Products to ensure that those products are marketed and sold in accordance with all applicable requirements;

e. all applicable legal rules (including the sanctions for violations) relating to marketing and sales of Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; the Medicaid Drug Rebate statute, and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples); and

f. examples of proper and improper marketing and sales practices.

After receiving the initial training described above, each Covered Person shall annually receive at least three hours of training on the topics outlined above.

To the extent that AstraZeneca has provided training that satisfies the requirements set forth above within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying, in part, AstraZeneca's training obligations as set forth in this Section III.C.2 for the first year of the CIA.

3. *Additional Training for Certain Covered Persons.* In addition to the training outlined in section III.C.2 above, within 120 days after the Effective Date, AstraZeneca shall provide 90 minutes of additional training (the "Additional Training") to those Covered Persons: 1) whose job responsibilities include complying with any requirements of the Medicaid Drug Rebate program; or 2) who are involved in the calculation or reporting of any pricing data or other related information for Government Reimbursed Products. To the extent that AstraZeneca has provided training that satisfies the Additional Training requirements set forth below within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying AstraZeneca's Additional Training obligations for the first year of the CIA.

This Additional Training shall include a discussion of:

a. the calculation and reporting of accurate pricing data and other information to CMS, the State Medicaid programs and drug price reporting services for Government Reimbursed Products (i.e., currently First DataBank, Inc., the Red Book);

b. the calculation and reporting of accurate pricing data and other information as required by the Medicaid Drug Rebate program;

c. the personal obligation of each individual involved in the calculation or reporting of drug pricing data or other information to ensure that prices are accurately calculated and reported;

d. all applicable legal rules (including the sanctions for violations) relating to proper calculation and reporting of drug pricing data for

Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute); and

e. examples of proper and improper drug price calculation and reporting practices.

After receiving the initial training described in this section, every Covered Person required to receive Additional Training shall receive at least one hour of Additional Training annually.

4. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Reporting Requirements.

1. *General Statement of Purpose and Intent.*

On a quarterly basis, AstraZeneca shall report to the entities identified below in section III.D.2.b certain pricing information, as specified below in section III.D.2.a, for the purpose of furnishing those entities with pricing information that accurately reflects prices at which actual purchasers buy the Covered Products sold by AstraZeneca. Such information shall be provided to the OIG subject to section IX and other conditions of this CIA, and AstraZeneca shall comply with section V.D in providing the data. The OIG agrees that, consistent with the provisions in section III.D.2.d below, if, and when, it shares the confidential pricing information with government agencies other than the OIG, it will encourage that the information not be used in a way that would competitively disadvantage AstraZeneca in relation to any of its competitors.

2. *Specific Reporting Requirements.*

a. *Average Sale Price Defined*

For purposes of this CIA, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Covered Products identified in Appendix A (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by AstraZeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers.") The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates;[3] and all other price concessions provided by AstraZeneca to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or bona fide grants.

AstraZeneca shall report the Average Sale Price by National Drug Code ("NDC") for each Covered Product by AstraZeneca's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, i.e., for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by AstraZeneca to a Relevant Purchaser, net of all price reductions identified above, for a Covered Product in a quarter by the total number of units of that product sold in that quarter.

b. *Reporting Obligations for Covered Products*

Except as otherwise noted below, 45 days after the last day of each calendar quarter, AstraZeneca shall report, in accordance with section III.D.2.a above, the Average Sale Prices for the Covered Products identified in Appendix A by AstraZeneca's NDC to: 1) the Medicaid programs of those States who have executed a state settlement agreement with AstraZeneca; 2) to First DataBank Inc.[4] solely for the purpose of

[3] The term "rebate" as used in this paragraph does not include any payments made by AstraZeneca to the States pursuant to the Medicaid Drug Rebate program (42 U.S.C. § 1396r-8).

[4] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their pricing information, AstraZeneca agrees that, upon the receipt of a written request by any of the States, it will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank Inc., subject to reasonable provisions equivalent to those agreed to by First DataBank Inc. to ensure the confidentiality of that

reporting pricing information based on those Average Sale Prices to the Medicaid programs of those States that have executed a state settlement agreement; 3) to CMS; and 4) to the OIG. The first report of Average Sale Prices shall be made no later than 45 days after the end of the first full calendar quarter following the Effective Date. The Average Sale Price reporting obligations of this CIA may be subject to modification consistent with a change in federal statutory or regulatory requirements pertaining to the submission of price information by pharmaceutical manufacturers.

c. *Certification Requirement*

In connection with each report of Average Sale Price, AstraZeneca shall also provide the OIG, CMS, and the applicable States a detailed description of the methodology used to calculate the Average Sale Prices. An appropriate employee or agent of AstraZeneca will certify that the Average Sale Prices reported are calculated in accordance with the described methodology. Said certifications shall be made in the form attached hereto as Attachment A. AstraZeneca agrees that this certification by an appropriate employee or agent of AstraZeneca constitutes a certification by AstraZeneca. To the extent that AstraZeneca's methodology involves accruing for the impact of future events, AstraZeneca shall include a description of its accrual methodology, including underlying assumptions, with its certification, and shall, on a quarterly basis, evaluate such accrual methodology in light of its actual experience and make any appropriate adjustments.

d. Confidentiality and Use of Reported Information

AstraZeneca and the OIG (on behalf of itself and CMS) acknowledge that the pricing information provided by AstraZeneca under this section III.D is considered to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of AstraZeneca. On behalf of itself and CMS, the OIG agrees to afford the pricing information disclosed by AstraZeneca the maximum degree of confidentiality permitted by law. CMS has been advised by the OIG of the purpose and use of the pricing information provided by AstraZeneca. Without surrendering any legal right to contest the use of this information, AstraZeneca acknowledges that this information may be relied upon by CMS in establishing

---

information.

reimbursement rates for AstraZeneca products, provided however that CMS will not change reimbursement rates for any AstraZeneca product based on this information without conducting meaningful review for all government-reimbursed therapeutically-similar products. Similarly, without surrendering any legal right to contest the use of this information, AstraZeneca acknowledges that the pricing information may be relied upon by State Medicaid programs in establishing reimbursement rates for AstraZeneca's products, subject to the provisions of the settlement agreements entered between AstraZeneca and various States as referenced in the Preamble to this CIA.

e. *Document Retention*

AstraZeneca shall retain all supporting work papers and documentation relating to the Average Sale Price of its Government Reimbursed Products for six years after the Effective Date and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the OIG or its duly authorized representative(s) in accordance with the provisions set forth more fully below in section VII of this CIA. However, the existence of any such privilege does not affect AstraZeneca's obligation to comply with the provisions of the CIA.

E. Review Procedures.

1. General Description.

During the term of the CIA, AstraZeneca shall retain either its own internal audit department or an independent review organization (IRO) to perform two types of reviews. The first relates to reported prices (Best Price and Average Sale Price) and the second relates to sales and marketing practices. Each type of review has two associated components – a systems review and sampling review of particular transactions. Generally speaking, the system reviews shall be conducted by the IRO for two Reporting Periods of the CIA. With one exception, the sampling reviews shall be conducted annually by the internal audit department.

a. Internal CIA Audit.

As set forth more fully in Attachment B, AstraZeneca may direct its Group Internal Audit ("GIA") to annually perform certain procedures to assist the company in assessing and evaluating its practices relating to the determination and reporting of Best Price for

purposes of the Medicaid Drug Rebate program ("Medicaid Rebate Review") and its sales and marketing practices ("Sales and Marketing Review"). Any reviews conducted by the GIA will be subject to verification by the Independent Review Organization (IRO) as set forth in Attachment C.

b. Retention of Independent Review Organization.

Within 120 days after the Effective Date, AstraZeneca shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "IRO"), to perform procedures as set forth in Attachment C to assist AstraZeneca in assessing and evaluating its drug price reporting systems and practices and its sales and marketing systems and practices. Each IRO must have expertise in auditing and in the requirements of the Federal health care programs as they relate to the reporting for, reimbursement of, and marketing/sales of Government Reimbursed Products. Each IRO shall assess, along with AstraZeneca, whether it can perform the engagements in a professionally independent and/or objective fashion, taking into account any other business relationships or other engagements that may exist.

c. *Types and Frequency of IRO Reviews.*

As specified more fully in Attachment C, AstraZeneca shall retain an Independent Review Organization ("IRO") to perform reviews to assist AstraZeneca in assessing and evaluating its systems, processes, policies and practices related to: 1) the determination of Best Price for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review"); 2) the methodology for calculating Average Sale Price ("Average Sale Price Systems Review"); and 3) its sales and marketing activities ("Sales and Marketing Systems Reviews").

If, during the term of the CIA, there are no material changes in AstraZeneca's systems, processes, policies and practices relating to the determination of Best Price, the calculation of Average Sale Price, or its sales and marketing activities, then the IRO shall perform the Systems Reviews outlined above to cover the first and fourth Reporting Periods. If AstraZeneca materially changes its systems, processes, policies or practices, then the IRO shall perform the applicable additional Systems Review(s) covering the Reporting Period(s) in which such changes were made in addition to conducting the Systems Reviews for the first and fourth Reporting Periods.

In addition to the Systems Reviews outlined above, for at least the first two years of the CIA, the IRO shall conduct the Average Sale Price Review outlined in Section D of Attachment C. After the IRO performs the Average Sale Price Review for the first two Reporting Periods of the CIA, AstraZeneca may, at its option, request the OIG to permit the Average Sale Price Review to be conducted by the GIA subject to verification by the IRO. The OIG retains sole discretion over whether to permit the Average Sale Price Review to be conducted by the GIA (subject to IRO verification) for subsequent years. In making its decision, the OIG will consider, among other factors, the results of the Average Sale Price Reviews for the first two Reporting Periods and AstraZeneca's demonstrated audit capabilities to perform the Average Sale Price Review internally. If the OIG denies AstraZeneca's request to shift the audit responsibilities, AstraZeneca agrees to engage the IRO to perform the remaining Average Sale Price Reviews.

d. Retention and Submission of Records.

For each year of the CIA, a complete copy of each of the GIA's and the IRO's Review Reports shall be included in AstraZeneca's Annual Reports to OIG. The GIA, the IRO and AstraZeneca shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports (those that are exchanged between the GIA and the IRO and AstraZeneca) relating to the engagements.

e. Submission of workplans

Prior to conducting their reviews, the GIA and IRO shall submit their workplan(s) to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the reports from the various reviews.

2. Validation Review.

In the event that the OIG has reason to believe that: (a) any of AstraZeneca's IRO or GIA Reviews fails to conform to the requirements of this CIA, or (b) the findings or reports from these Reviews are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Review in question complies with the requirements of the CIA and/or the reported findings for the Review are inaccurate ("Validation Review"). AstraZeneca shall pay for the reasonable cost of any such review performed

by the OIG or any of its designated agents so long as it is initiated within one year after AstraZeneca's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify AstraZeneca of its intent to do so and provide an explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, AstraZeneca may request a meeting with the OIG to discuss the results of any Review submissions or findings; present any additional or relevant information to clarify the results of the Review or to correct any inaccuracies; or propose alternatives to the proposed Validation Review. AstraZeneca shall produce any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any IRO or GIA Review issues with AstraZeneca prior to conducting a Validation Review. However, the final determination as to whether to proceed with a Validation Review shall be made at the sole discretion of the OIG.

3. Independence Certification.

The IRO shall include in its reports to AstraZeneca a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, and that it has concluded that it is, in fact, independent and/or objective. The first such certification shall be included in the Implementation Report.

F. Disclosure Program.

AstraZeneca presently has a Disclosure Program designed to facilitate communications relating to compliance with the law and AstraZeneca's policies. During the term of the CIA, AstraZeneca shall maintain its Disclosure Program, which includes a mechanism (the toll-free Code of Conduct Ethics Helpline) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with AstraZeneca's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. AstraZeneca shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure associated with AstraZeneca's policies, conduct, practices or procedures with respect to any Federal health care program or Federal health care program requirement ("Disclosure"), the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every Disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any Disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, AstraZeneca shall conduct an internal review of the allegations set forth in such a Disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a Disclosure log, which shall include a record and summary of each Disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The Disclosure log shall be available to OIG, upon request.

G. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred, suspended or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that is governed by 42 U.S.C. § 1320a-7(a) related to the provision of health care items or services, but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

2. *Screening Requirements.* AstraZeneca has a policy to not hire or engage as a Covered Person any Ineligible Person, and it shall maintain that policy during the term of the CIA. To prevent hiring or engaging any Ineligible Person, AstraZeneca shall screen all prospective Covered Persons prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded

Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, to the extent not already accomplished, AstraZeneca shall review its list of current Covered Persons against the Exclusion Lists. Thereafter, AstraZeneca shall review the list annually. In addition, AstraZeneca shall require Covered Persons to disclose immediately any debarment, exclusion, suspension or other event that makes the individual an Ineligible Person.

If AstraZeneca has actual notice that a Covered Person has become an Ineligible Person, AstraZeneca shall remove such person from responsibility for, or involvement with, AstraZeneca's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If AstraZeneca has actual notice that a Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, AstraZeneca shall take all appropriate actions to ensure that the Covered Person's continued performance of his or her responsibilities shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, AstraZeneca shall notify OIG, in writing, of any ongoing investigation known to AstraZeneca or any legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that AstraZeneca has committed a crime or has engaged in fraudulent activities in the United States. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. AstraZeneca shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. Reporting of Reportable Events.

1. *Definition of Reportable Event.*

For purposes of this CIA, a "Reportable Event" means anything that involves a matter, brought to the attention of senior management at AstraZeneca's corporate headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If AstraZeneca determines through any means that there is a Reportable Event, AstraZeneca shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to the OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of AstraZeneca's actions taken to correct the Reportable Event; and

iii. any further steps AstraZeneca plans to take to address the Reportable Event and prevent it from recurring.

3. AstraZeneca shall not be required to report any Reportable Event that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under section III.H. above.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, AstraZeneca establishes or acquires new business units engaged in the contracting for, marketing, sales or price reporting of Government Reimbursed Products, AstraZeneca shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of the establishment or acquisition. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding contractor's name and address that has issued each provider number. All new Covered Persons at such business units shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, AstraZeneca shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, position description of the Compliance Officer required by section III.A.1, and summary of other non-compliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Business Compliance Committee required by section III.A.2;

3. a copy of AstraZeneca's Code of Conduct and the accompanying letter required by section III.B.1;

4. to the extent not already provided, a copy of all Policies and Procedures required by section III.B.2;

5. to the extent not already provided, a copy of all training materials used for the training required by section III.C, a description of such training programs including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, and schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Conduct and accompanying letter certification required by section III.B.1;

c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by section III.F;

8. a summary/description of all reviews to be completed by GIA and the proposed start and completion date of the first reviews; the identity of the IRO(s); a summary/description of all engagements between AstraZeneca and the IRO, including, but not limited to, any outside financial audits or other audits, and the proposed start and completion dates of the first IRO reviews;

9. a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.G;

11. except for home offices, a list of all of AstraZeneca's locations (including locations and mailing addresses) at which Covered Persons work, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s) and the contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of AstraZeneca's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. AstraZeneca shall submit to OIG Annual Reports with respect to the status of, and findings regarding, AstraZeneca's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. as described in section III.A, any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Business Compliance Committee;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct and accompanying letter certifications required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C; and

c. AstraZeneca's Policies and Procedures and its templates for the standardized contracts and other similar documents have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed.

The documentation supporting this certification shall be available to OIG, upon request.

To the extent that the Compliance Officer cannot certify to these items in their entirety, the Compliance Officer shall provide an explanation of any deficiencies and a timetable for their remedy.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in Federal health care program requirements) and copies of any Policies and Procedures;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided), a description of such training conducted during the Reporting Period, including a list of targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the GIA's and IRO's Reviews required by this CIA, including, to the extent not already provided, a copy of the methodologies used, along with a copy of the IRO's engagement letter;

6. AstraZeneca's response and corrective action plan(s) related to any issues raised by the GIA and IRO(s) reviews;

7. a revised summary/description of all engagements between AstraZeneca and the GIA and IRO, as described in section V.A.8, if different than what was submitted as part of the Implementation Report; for the second and subsequent Reporting Periods, a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca.

8. a summary of the Disclosures in the Disclosure log required by section III.F;

9. a description of any personnel actions (other than hiring) taken by AstraZeneca as a result of the obligations in section III.G, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under section III.G, and the actions taken in response to the obligations set forth in that section;

10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

11. a summary of any Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

12. a description of the co-promotion agreements that AstraZeneca has with other firms, including the number of such agreements in existence during the Reporting Period and a summary of the assurances AstraZeneca has received regarding the training of co-promotion personnel, as referenced in Section II;

13. a description of all changes to the most recently provided list (as updated) of AstraZeneca's locations except home offices as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

14. the certification required by section V.C.

The first Annual Report shall be submitted to the OIG no later than 90 days after the end of the first Reporting Period. Each subsequent Annual Report shall be submitted to OIG no later than 90 days after the end of each subsequent Reporting Period.

C. Certifications.

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, AstraZeneca is in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information therein is accurate and truthful.

D. Designation of Information.

AstraZeneca shall clearly identify any portions of any of its submissions under this CIA that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. AstraZeneca shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone: (202) 619-2078
Fax: (202) 205-0604